General Guidelines for Non-Profit Institutional Human Specimen/Patient Data Transfer Policies

Manoja Ratnayake Lecamwasam PhD

Director, Intellectual Property and Innovation

St Joseph's Hospital and Medical Center/Catholic Healthcare West

Phoenix, AZ

January 31, 2007

What Is Covered Under a Human Specimen/Patient Data Policy?

- Tissues
- Blood
- Serum
- DNA
- Other biological material
- Patient data

Human Specimen/Patient Data Transfer Monitoring Committee

- Formation of a committee to:
  - Establish a human specimen/patient data transfer policy
  - Oversee the implementation of such policy on a institution-wide basis
  - Establish guidelines for acceptable transfers of human specimen/patient data to third parties
  - Review transfers that fall outside of established policies and guidelines

Underlying Assumptions

- Use and transfer of human specimens/patient data is consistent with the mission of the non profit institution
- Transfer of human specimens/patient data is consistent with all applicable regulatory laws and policies:
  - Informed consent
  - Common Rule
  - HIPAA Privacy Rule
  - Absence of Conflict of Interest
  - IRB Approval, if needed
- Use of Material Transfer, Clinical Trial or Research Collaboration Agreements to establish transfer conditions and obligations

Intellectual Property Rights (Issues To Consider……)

- Ownership of human specimens/patient data
- Access research data and results
- Inventions and patent rights
- Publication rights
- Freedom to distribute human specimens/patient data

Ownership of Human Specimen/Patient Data

- Donor institution should retain title and all rights to the unmodified human specimens and/or patient data being transferred to a third party
- Any other rights granted to a recipient institution/company for any form of human tissue/patient data should be governed by an appropriate contract executed by both parties

Access to Research Data and Results

- Donor institution should consider requesting access to research results and/or data that is obtained using the transferred human specimens/patient data
  - Collaboration – data sharing; internal research or commercial purposes
  - Direct transfer – access to data/results at least on a confidential basis; for information or internal research purposes

Inventions and Patent Rights

- Inventorship of any invention made or reduced to practice as a result of donor institution human specimens/patient data transfer:
  - Can be determined according to US patent law
    - Ownership would follow inventorship
    - Should be as per a contract signed by all involved parties
  - Can grant outright rights to inventions and any results obtained from any research performed using donor institution human specimens/patient data to recipient institution/company
    - Rights should be granted under a contract signed by all involved parties

Publication Rights

- Collaboration
  - joint publication rights
  - Appropriate citation of contribution of each party
- Outright transfer (without joint research collaboration)
  - Acknowledgement of donor institution's contribution of human specimen/patient data

Freedom to Distribute Human Specimens/Patient Data

- Donor institutions should strongly consider:
  - retaining the right to transfer their human specimens/patient data to any third party for any purpose
  - Ensuring that the tissue is not re-transferred to another entity (especially for-profit) by the recipient institution/company without written consent from donor institution.

Points to Take Away

- Form an overseeing committee to establish policies and address issues relating to such policies
- Establish a human specimen/patient data policy outlining the obligations/conditions that are required under established laws and institutional policies
- Be prepared that there will always be unique and unexpected specimen/data transfer situations